Department of Health and Human Services | Public Health Service

Food and Drug Administration
Rockville, MD 20857

JUN 1 2012

Re: Kepivance
Docket No. FDA-2005-E-310

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is concerning the patent term extension application for U.S. Patent No. 5,677,278 filed by Chiron Corporation under 35 U.S.C. 156. The patent claims Kepivance (palifermin), which was assigned biologics license application (BLA) 125103.

In the *Federal Register* of April 2, 2007 (72 FR 15699), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. 156(d)(2)(A). The notice provided that on or before October 1, 2007, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

In a letter dated May 24, 2007, Arnold & Porter LLP, on behalf of Novartis Vaccines and Diagnostics, Inc., requested revision of the regulatory review period as published in the April 2, 2007, *Federal Register* notice. However, by letter dated March 20, 2012, FDA affirmed the determination of the regulatory review period as published and denied the request for regulatory review period revision for Kepivance.

The 180-day period for filing a due diligence petition under this notice has expired and FDA has received no additional petitions. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Vinola Milan
Arnold & Porter, LLP
555 Twelfth St., NW
Washington, DC 20004-1206